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Atty. Dkt. No. 024407-0102

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Crystal WATKINS et al.

Title: METHODS FOR PREVENTION AND  
TREATMENT OF  
GASTROINTESTINAL DISORDERS

Appl. No.: 09/840,014

Filing Date: 04/19/2001

Examiner: RUSSEL, Jeffrey E.

Art Unit: 1654

**DECLARATION UNDER 37 C.F.R. § 1.131**

Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

Sir:

We, Crystal C. Watkins, Solomon H. Snyder and Christopher D. Ferris, being duly warned, declare as follows:

- (1) We are co-inventors of the above-captioned application.
- (2) The Examiner has rejected claim 57 under 35 U.S.C. 102(a), as being anticipated by Bortolotti et al., *Gastroenterology*, Vol. 118, pages 253-257 ("the Bortolotti article").
- (3) We conceived and reduced to practice the above-captioned application's claimed invention in a WTO country prior to the publication date of the Bortolotti article. To support this attestation, attached as Exhibits A and B, respectively, are copies of Watkins et al., *The Journal of Clinical Investigation*, Vol. 106, No. 3, pages 373-384 ("the Watkins article"), and a letter from co-inventor Solomon H. Snyder to the editor of the *Journal of Clinical Investigation* ("the Snyder letter").

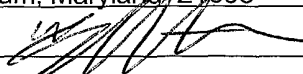
(4) The co-authors of the Watkins article include the inventors of the above-captioned application. As established in the Declaration under 37 C.F.R. 1.132, originally submitted to the Office on April 7, 2003 and resubmitted herewith, the other co-authors, namely, Roxanne K. Barrow and Akira Sawa, did not participate in the conception or make an inventive contribution to the claimed invention.

(5) The Watkins article presents experimental data showing that treatment of diabetic mice with sildenafil reverses delayed gastric emptying (see, for example, Figure 8). The Watkins article further mentions that sildenafil and other PDE inhibitors "may be effective in the treatment of diabetic gastropathy and related conditions" (see page 383, first paragraph).

(6) The Watkins article was received for publication on August 27, 1999. Although the Watkins article was accepted in *revised* form on June 27, 2000, the sildenafil experiments described in the Watkins article were completed before the publication date of the Bortolotti article. As evidence, the Snyder letter states at page two, third full paragraph: "Accordingly, we have treated diabetic mice with sildenafil ... and observed restoration of normal gastric function." While the date of the Snyder letter has been redacted, it is prior to the publication date of the Bortolotti article.

(7) We further declare that all statements made herein of our own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements and the like so made may jeopardize the validity of this declaration, the subject application, or any patent issuing thereon.

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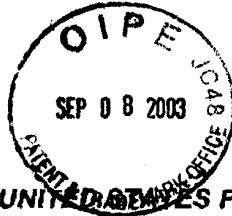
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